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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/510,451

10/04/2004

Russell Heinrich

2797

2284

7590

12/11/2006

Paul R Audet
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EXAMINER

ANDERSEN, MICHAEL T

ART UNIT

PAPER NUMBER

3734

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/510,451 | Applicant(s) HEINRICH, RUSSELL | |
| | Examiner M. Thomas Andersen | Art Unit 3734 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/04/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,32-46,52-54 and 67-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7-31,47-51,55-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/06/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Acknowledgement is made of the claim to benefit of provisional application number 60/373,224, filed on 4/16/2002.

Information Disclosure Statement

The information disclosure statement (IDS) received on 12/06/2004 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Election/Restrictions

Restriction to one of the following inventions was required under 35 U.S.C. 121:

- I. Claims 1-4, 7-31, 47-51 and 55-66, drawn to a surgical staple and wound closure material applicator, classified in class 606, subclass 219.
- II. Claims 5-6, 32-46, 52-54 and 67-74, drawn to tissue cauterization by electrical energy, classified in class 606, subclass 32.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related surgical staplers. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are not obvious variants because electrical application is not typically used with wound closure material application. Furthermore, the inventions as

Art Unit: 3734

claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Kimberly Perry on 11/29/2006 a provisional election was made without traverse to prosecute the invention of the wound closure applicator, claims 1-4, 7-31, 47-51 and 55-66. Affirmation of this election must be made by applicant in replying to this Office action. Claim 5-6, 32-46, 52-54 and 67-74 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 55 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "a body tissue property enhancing system configured and adapted to non-mechanically enhance..." is unclear and not defined adequately in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7-31, and 47-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolanos, U.S. Patent No. 5,897,562, in view of Whitman, U.S. Patent No. 6,488,197.

Bolanos discloses a surgical stapler, and corresponding method, comprising an anvil, a staple cartridge, a working surface, rows of individual staple slots, a plurality of staples, a driving member, a plurality of deployable needles to penetrate a layer of adjacent tissue. See figures 3 and 5C-5D.

Bolanos does not expressly disclose a body tissue enhancing system comprising a biocompatible wound closure material. However, Whitman recognizes the need of such a device. "Another failure is that the prior art devices provide no means to allow the delivery of fluid to the site of the freshly cut tissue. Medicine or other substances which accelerate the healing process, if delivered to the site simultaneous with or subsequent to the stapling and cutting process, could speed healing of the tissue or perform other medical functions." Whitman, col. 2, lines 48-53. In view of Whitman, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide means to allow for the delivery of medicine to the freshly cut and stapled tissue. In order to deliver the medicine "to the site simultaneous[ly] with or subsequent to the

Art Unit: 3734

stapling and cutting process," it would have been obvious to include a wound closure material to the plurality of ducts (e.g. 302, figure 5C) in Bolanos in view of the teachings of Whitman.

Further, the needles or pins in Bolanos are biased in a first position not extending out of ducts 302.

Claims 55-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitman, U.S. Patent No. 6,488,197, in view of Bolanos, U.S. Patent No. 5,897,562.

Whitman discloses a handle assembly, a tubular body portion, a staple cartridge assembly including a pair of annular arrays of staple receiving slots, an anvil member and a tissue property enhancing system adapted to deliver an amount of biocompatible wound closure material. Whitman does not disclose the use of needles in addition to staples. However, Bolanos discloses the use of needles or "dart members" to "precondition the tissue to be joined." Bolanos, col. 7, lines 20-21. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply pins or dart members to Whitman in order to "precondition the tissue," as taught by Bolanos. Preconditioning the tissue and using a wound closure material combines the advantages of Whitman and Bolanos and serves to speed up the wound closing process.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tucker, U.S. 5,895,412, disclosing a tissue sealant.

Art Unit: 3734

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Thomas Andersen whose telephone number is (571) 272-8024. The examiner can normally be reached on M-F 8AM-4:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Thomas Andersen

December 7, 2006

A handwritten signature in black ink, appearing to read "M J Hayes", with a long horizontal flourish extending to the right.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER